

**REMARKS**

Upon entry of the foregoing amendment, claims 1-2, 7, 8, 9-14, 15-29, 30-34, 37-43, 45-49, 51, 52, 54, 57-64, 67, 68, 74-77, 79, and 80 are pending. Claims 15-29, 45-49, 51, 59-64, 74-77, 79, and 80 have been withdrawn from examination as being directed to a non-elected invention. Claims 3-6, 35, 36, 44, 50, 53, 55, 56, 65, 66, 69-73, and 78 have been canceled. Claims 1-2, 7-14, 30-34, 37-43, 52, 54, 57, 58, 67, and 68 have been amended and are currently under examination.

Claims 1, 11, 34, and 52 are amended to correct typographical errors in the spelling of "*Mortierella alpina*" (claims 1, 11, and 34) and in the spelling of "microorganism" (claim 52). Support for this amendment can be found, for example, on page 12, line 33 through page 13, line 4; and, elsewhere throughout the specification. In claim 11, the designation of the microorganism has been corrected. Support for the amendment is found, for example, in original claim 1; and, elsewhere throughout the specification.

Claims 2, 7, 8, 9, 10, 12-14, 39, 40, 41, 52, 54, 57, 58, 67, and 68 are amended to change the phrase "according to" to "of" for reasons of consistency. Claims 7, 8, 9, 12-14, 30-34, 37-39, 42, 43, 54, 57, 58, 67, and 68 are also amended to further clarify the claimed invention and to bring the claims more closely into conformance with U.S. patent practice.

Claims 14, 34, 42, and 57 have been amended to delete the term "contains" and recite instead the term "comprises" or "comprising." Support for the amendments is found, for example, in original claims 34 and 41; page 16, lines 23-31; and, elsewhere throughout the specification.

Claim 39 has been amended to more clearly claim the invention. Support for the amendments to the claim are found, for example, on page 21, lines 15-24; and, elsewhere throughout the specification.

Lastly, claims 3-6, 35, 36, 44, 50, 53, 55, 56, 65, 66, 69-73, and 78 have been previously canceled without prejudice or disclaimer to the subject matter recited therein. Applicants wish to clarify (in response to request for clarification from the Examiner) that claims 72 and 73 have been canceled. Applicants reserve the right to file one or more continuation application(s) directed to the canceled or amended subject matter. No prohibited new matter is believed to have been added by the present amendment.

The amendments to the claims are believed to put the claims in condition for allowance, or alternatively, in better form for Appeal. Thus, entry of the amendment is believed to be proper and is respectfully requested.

#### **REQUEST FOR INTERVIEW BEFORE MAILING OF THE ADVISORY ACTION**

The arguments and reasons provided below are believed to overcome all standing rejections. If, however, one or more claims remain rejected, Applicants respectfully request an interview, either in person or telephonic, with the Examiner before the Advisory Action is mailed. Applicants believe any concerns the Examiner may have can be easily and quickly be addressed and overcome. In view of the desire of the Patent Office to reduce pendency and provide good customer service, an interview with Applicants' representatives is appropriate.

#### **OBJECTIONS TO THE CLAIMS**

At page 2 of the Office Action, the Examiner has indicated that the following objections will be made should certain of the claims be found allowable:

(1) Claims 2, 7-14, 34 and 37-41 will be objected to as being substantial duplicates of claim 1 "because defining a microorganism in two claims in terms of its characteristics, or how it is made or obtained does not require a different microorganism." *See*, Office Action (mail dated 12/13/04) at 3.

(2) Claims 65-68 will be objected to as being substantial duplicates of claims 30-33 because "method [c]laims 65-68 require the same method steps and same microorganism strain as in the method claims 30-34." *See*, Office Action (mail dated 12/13/04) at 3.

(3) Claims 72-73 will be objected to as being substantial duplicates of claims 42-43 because "method [c]laims 72 and 73 require the same method steps as in the method claims 42 and 43." *See*, Office Action (mail dated 12/13/04) at 3.

Applicants disagree with the position of the Office. The Office is reminded that Applicants are entitled to be their own lexicographer, using the language of their choice to claim the invention. *See*, M.P.E.P. § 2111.01, III, page 2100-50, Rev. 3, August 2005. Applicants may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter

for which protection is sought. *See*, M.P.E.P. § 2173.01 “Claim Terminology,” Rev. 3, August 2005. Court decisions have confirmed Applicants’ right to re-state (*i.e.*, by plural claiming) the invention in a reasonable number of ways. **Indeed, a mere difference in scope between claims has been held to be enough.** (Emphasis added)(M.P.E.P. § 706.03(k) “Duplicate Claims” page 700-74, Rev. 3, August 2005).

Contrary to Office arguments, there are no pending claims which are believed to be “substantial duplicates.” A fair reading of the pending claims, both previously and as amended herein, reveals that each pending claim is of differing scope. Therefore, there are no claims which are “substantial duplicates.”

**Regarding (1) above:**

Claims 2, 7-14, 34, and 37-41 will be objected to as allegedly being substantial duplicates of claim 1, "because defining a microorganism in two claims in terms of its characteristics, or how it is made or obtained does not require a different microorganism."

However, contrary to the position of the Office, claim 2 (correctly) further limits claim 1, and therefore has a different scope. Since claims 1 and 2 are of differing scope, they do not claim the same invention and thus are not substantial duplicates

**Regarding (2) above:**

Claims 65-68 will be objected to as allegedly being substantial duplicates of claims 30-33 because “method [c]laims 65-68 require the same method steps and same microorganism strain as in the method claims 30-34.” Claims 65 and 66 have been canceled. Contrary to the position of the Office, claiming the same method steps and same microorganism does not make them duplicates. Claims 67 and 68 differ from each other in that claim 67 recites a method for producing a lipid, while claim 68 recites a method of producing an unsaturated fatty acid. Fatty acids are a subset of the genus of lipids. Therefore, the claims differ in scope. Indeed, claim 68 requires separating the fatty acids from the lipids produced by the microorganism. Claims 67 and 68 clearly are not duplicates.

Claims 30-33 depend from claim 1, while claims 67 and 68 depend from claim 34. Claim 1 and claim 34 are not duplicates since claim 34 describes the composition of the lipid and claim 1 does not. The Office is reminded that Applicants are entitled to claim the invention in a reasonable number of ways.

**Regarding (3) above:**

Claims 72 and 73 are canceled, thus mooting the objection.

If the Office maintains this objection, the Office is respectfully requested to provide in writing an explanation of the reasons why, for example, claims 1 and 2, are considered substantial duplicates so that Applicants can address the specific issues and expedite prosecution and allowance. Reconsideration and withdrawal of the objection is respectfully requested.

**Rejection under 35 U.S.C. § 112, second paragraph**

Applicants acknowledge with thanks the withdrawal of the rejection.

**Rejection under 35 U.S.C. § 102(b)**

The Office has maintained the rejection of claims 1, 2, 7, 11-14, 30, 34, 37, 41, 42, 52, 54, 58, 67, and 68 under 35 U.S.C. § 102(b) as purportedly being anticipated by Shinmen *et al.* (EP 0 276 982 A2) ["Shinmen"]. *See*, Office Action at 3. The rejection is respectfully traversed.

For prior art to be anticipatory under section 102, the Federal Circuit has held that every element of the claimed invention must be disclosed in a single item of prior art in the form literally defined in the claim. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 213 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Shinmen discloses culturing a microorganism in a liquid culture medium. The culture containing the microorganism is then sonicated in order to obtain a homogenate. The homogenate is used as an enzyme solution in reactions to produce highly unsaturated fatty acids. *See*, for example, Shinmen Examples 1-3. The substrates added to the reaction mixture are the precursor molecules to the unsaturated fatty acids. *See*, for example, Shinmen, page 5, line 50 through page 6, line 1. Shinmen teaches the use of the homogenate as a source of enzymes to convert exogenously added precursor fatty acids to highly unsaturated fatty acids. Shinmen does not teach the use of the homogenate **as a source of lipids or lipid vesicles**. The attention of the Office is directed, for example, to the Shinmen Abstract for a concise summary of the teachings of Shinmen.

Contrary to the arguments of the Office, Shinmen does not teach, either explicitly or inherently, a microorganism that secretes unsaturated fatty acid-containing lipid vesicles. In fact, there is not a single literal recitation of the phrase "lipid vesicles," or, any discussion of secretion of lipid vesicles in Shinmen. As such, Shinmen does not teach, explicitly or inherently, each and every element of independent claims 1, 11 and 34. Therefore, Shinmen does not anticipate independent claims 1, 11 and 34, and claims dependent therefrom.

The Office has maintained the rejection for reasons set forth in the Office Action mail dated November 30, 2004 and for additional reasons set forth in the instant Office Action. Applicants presume the Examiner is referring to the Office Action mail dated December 13, 2004 since a November 2004 Office Action is not of record.

The reasons for rejection stated in the December 2004 Office Action are not applicable to the currently pending claims because: 1) the current claims are directed to a different microorganism than is described in Shinmen (Shinmen does not describe *M. alpina* SAM 2241 or *M. alpina* SAM 2242 as is currently claimed); and, 2) Shinmen describes using the homogenate made from the cultured microorganisms as a source of enzymes, and does not describe secretion of lipid vesicles.

The current Office arguments regarding the teachings of Shinmen are also erroneous. At page 6 of the 12/13/04 Office Action, the Office (citing to Shinmen, page 2, lines 16-43; page 3, line 58; and page 7, lines 33-65) states "Shinmen teaches a *Mortierella* microorganism, *Mortierella elongate* SAM 0219 that produces lipids when cultured in a liquid or on a solid medium." The Office statement is a misstatement of the teachings of Shinmen.

Contrary to the arguments of the Office, the teachings of Shinmen, for example, at page 2, lines 16-43, are directed to a method of producing a mixture of highly unsaturated fatty acids in a reaction mixture using enzymes, not secretion of lipids or lipid vesicles. In Shinmen, the method comprises, *inter alia*, using the product derived from the cells (identified elsewhere in Shinmen as enzymes) to obtain a reaction mixture (step 2) and converting the precursor substances (which are exogenously added fatty acids) to highly unsaturated fatty acids in the presence of the intact cells or the product derived from the cells (*i.e.*, enzymes). Producing highly unsaturated fatty acids in a reaction mixture via enzymatic reactions using exogenously fatty acid precursor molecules and homogenate-derived enzymes is very different than producing lipid vesicles by production and secretion of fatty acids. Moreover, there is no teaching or suggestion in Shinmen that the Shinmen microorganisms are capable of producing and secreting lipid vesicles.

The Office arguments directed to the teachings of Feit *et al.* at page 4 of the instant Office Action are immaterial because Shinmen clearly fails to teach each and every element of independent claims 1, 11, and 34. If the Office maintains this rejection, the Office is respectfully requested to explain in detail:

- 1) where Shinmen teaches or suggests a microorganism which secretes lipids in lipid vesicles absent any mention in Shinmen of lipid secretion and lipid vesicles;
- 2) why producing highly unsaturated fatty acids in a reaction mixture via enzymatic reactions using exogenously fatty acid precursor molecules and homogenate-derived enzymes is the same as producing lipid vesicles by secretion of fatty acids; and,
- 3) how Shinmen, which is silent on production and secretion of lipids and lipid vesicles, teaches
  - a) secretion of lipids in lipid vesicles is a certain event (Feit factor number 1, Office Action at 3),
  - b) that production and secretion of lipids in lipid vesicles necessarily results as opposed to a possibility (Feit factor number 1, Office Action at 3);
  - c) that production and secretion will always happen (Feit factor number 2, Office Action at 3); and,
  - d) that a person having ordinary skill in the art would recognize the missing descriptive material is necessarily present (Feit factor number 3, Office Action at 3) in Shinmen.

In view of the above, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Additionally, claims 1-2, 7, 11-14, 30, 34, 37, 41, 42, 52, 54, 58, 67, and 68 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Shinmen *et al.* (EP 0 276 982). *See*, Office Action at 4. The rejection is respectfully traversed.

Applicants' arguments made above regarding the rejection under 35 U.S.C. § 102(b), above, are relevant to this rejection as well and are incorporated herein in their entirety. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Additionally, Applicants point out that which is inherent in the prior art, if not known at the time of the invention, cannot form a proper basis for rejecting the claimed invention as obvious under

section 103. *See In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 756-757 (C.C.P.A. 1977). “[T]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *Id.*, at 566 F.2d 86, 195 U.S.P.Q. at 757. Therefore to use Shinmen in support of a rejection under 35 U.S.C. § 103, is in error in view of how it was asserted by the Office in its rejections under 35 U.S.C. § 102.

At page 4 of the Office Action, the Office relies upon the arguments set forth in the Office Action mail dated 12/13/04 in maintaining the rejection. The Office argues that claims recite a *Mortierella elongata* SAM 0129 organism. *See*, 12/13/04 Office Action at page 6. The Office arguments are wrong, because claims 1, 11, and 34 clearly claim strain *Mortierella alpina* SAM 2241 or *Mortierella alpina* SAM 2242. Thus, the claimed microorganisms are different from the microorganism taught by Shinmen.

The Office argues that Shinmen teaches the claimed methods. *See*, 12/13/04 Office Action at page 6. The Office arguments are wrong, because Shinmen teaches production of lipids via enzymatic reactions in extracellular reaction mixtures and not secretion of lipids in lipid vesicles.

The Office argues that “[t]herefore, the prior art method inherently must be producing said lipids in same fashion as claimed because a process comprising same ingredients (i.e., culture media and microorganism strain) and steps (i.e., fermentation in a liquid medium comprising same precursor fatty acids or on a solid medium comprised of same ingredients) is being applied as is recited in the claimed invention (citation omitted).” *See*, 12/13/04 Office Action at page 6. The Office arguments are wrong, because the processes taught by Shinmen are directed to, *inter alia*, production of lipids via enzymatic reactions in extracellular reaction mixtures and **not to internal production of lipids and secretion of lipids in lipid vesicles**. If the Office maintains this argument, the Office is respectfully requested to explain how internal production of lipids and secretion of lipids and lipid vesicles is “the same process” as enzymatic production of lipids.

In formulating the rejection under 35 U.S.C. § 103, the Office has relied solely upon the teachings of Shinmen. However, Shinmen does not teach or suggest an isolated microorganism which extracellularly secretes an unsaturated fatty acid-containing lipid as lipid vesicles encapsulating said lipid, wherein said microorganism is *Mortierella alpina* SAM 2241 or *Mortierella alpina* SAM 2242, as is claimed in independent claims 1, 11, and

34. As such, Shinmen does not teach or suggest all of the claim limitations. Thus, the Office has failed to set forth a legally proper *prima facie* case of obviousness.

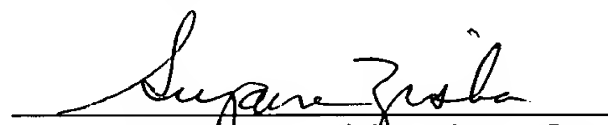
In view of the legally deficient *prima facie* case of obviousness, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

### **CONCLUSION**

In conclusion, this amendment and reply is believed to be a full response to the outstanding Office Action. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or Notice of Appeal fees, or credit any overpayment to Deposit Account No. 50-0573. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3). This paragraph is also intended to serve as a Notice of Appeal should the formal document become separated or lost.

Respectfully submitted,

  
Suzanne E. Ziska, Ph.D., Esq.  
Registration No. 43,371

Date: March 1, 2006

DRINKER BIDDLE & REATH LLP  
1500 K Street, N.W, Suite 1100  
Washington, D.C. 20005-1209  
Tel: (202) 842-8800  
Fax: (201) 842-8465